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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,768	01/18/2002	Uwe Hahmann	2565.94	7106

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EXAMINER

KIM, SUN U

ART UNIT PAPER NUMBER

1723

DATE MAILED: 06/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/052,768

Applicant(s)
Hahmann et al.

Examiner
John Kim

Art Unit
1723



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 14, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-58 is/are pending in the application.
- 4a) Of the above, claim(s) 55-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Jan 18, 2002 is/are a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/441,182.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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1. Applicant's election with traverse of Group I (claims 24-54) in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the subject matter of the claims is such that there would be no serious burden on the examiner to search and examine all of the claims at the same time. This is not found persuasive because Group I and II are distinct inventions as described in the paragraph 3 of the Paper No. 5 and acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter as shown in the paragraph 4 of the Paper No. 5. Group I does not require search in class 604, but Group II would require search in class 604.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 55-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 7.

3. The drawings are objected to because Figures 1A, 1B, 2A and 2B need to be separately labeled. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the filter module of dialysis, hemofiltration and ultrafiltration with a plurality of connections must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

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A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 20 and 30 in Figure 1B, 200 and 202 in Figure 2A, 141 and 143 in Figure 2B, 204 in Figure 3, 206 in Figure 4, 210 in Figure 6. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 24-26, 31-32, 34, 36, 38, 40-42, 46-47, 49, 51 and 53 are rejected under 35

U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,197,848 (hereinafter referred to as

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Garrett et al). Garrett et al teach a closure element (42, 46) in a medical device comprising a resilient wall (42) with a resiliently deformable slit (56) and a cylindrical integral skirt (46) wherein wall and skirt are made of latex and resilient slit prevents entry of air (see figures 1-4; col. 4, line 37 - col. 5, line 18). Lip (36), inner and outer annulus (34, 38) hold the closure element (42, 46) and thus, satisfies the means for fastening the closure element to a connecting element (see col. 4, lines 23-48).

9. Claims 35 and 50 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Garrett et al. Garrett et al teaches a closure element (42, 46) in a medical device as described in above paragraph 8. Although Garrett et al does not explicitly disclose the claimed limitation of a slit being adapted to withstand a pressure difference up to about plus or minus 0.25 bar, it is PTO's position that the slit (56) of Garrett et al has inherent capability to withstand a pressure difference up to about plus or minus 0.25 bar. See *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977).

10. Claims 27, 33, 37, 39, 43, 48, 52 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garrett et al. Regarding claims 27 and 43, Garrett et al discloses the claimed invention except for slit-shaped indentation in a shape of a cross or a star. It would have been an obvious matter of design choice to modify the slit of Garrett et al in a shape of cross or a star, since applicant has not disclosed that slit indentation in a shape of cross or a star solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with a slit in any shape. Regarding claims 33 and 48, Garrett et al meets the limitation except

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that the wall and the closure element is made of resilient, liquid and air impervious material such as latex or other similar material rather than silicone. However, because these latex or other similar materials and silicone were art-recognized equivalents at the time of the invention in a sealant material, one of ordinary skill would have found it obvious to substitute silicone as sealing closure material for latex or other similar material. Regarding claims 37, 39, 52 and 54 it would have been obvious to a person of ordinary skill in the art to incorporate a closure element of Garrett et al in a common medical filter module such as a dialyzer, hemofilter and ultrafiltration filters with a plurality of connections for providing sterile connections between a tubing and the filter module.

11. Claims 24, 26, 28-29, 32-34, 36, 38, 40, 42, 44, 47-49, 51 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,929,235 (hereinafter referred to as Merry et al). Merry et al teach a closure element (26, 29) in a medical device comprising a first gasket (26) with a resiliently deformable Y-slit (27) and a second gasket (29) with a central opening (31) wherein gaskets are made of silicone and resilient slit prevents entry of air (see figures 1-4; col. 4, line 37 - col. 5, line 18). Spacer ring (28) and valve body (11) hold the closure element (26, 29) and thus, satisfies the means for fastening the closure element to a connecting element (see figure 1).

12. Claims 35 and 50 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Merry et al. Merry et al teaches a closure element (42, 46) in a medical device as described in above paragraph 11. Although Merry et al

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does not explicitly disclose the claimed limitation of a slit being adapted to withstand a pressure difference up to about plus or minus 0.25 bar, it is PTO's position that the slit (27) of Merry et al has inherent capability to withstand a pressure difference up to about plus or minus 0.25 bar. See *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977).

13. Claims 27, 30, 43 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merry et al. Regarding claims 27 and 43, Merry et al discloses the claimed invention except for slit-shaped indentation in a shape of a cross or a star. It would have been an obvious matter of design choice to modify the slit of Merry et al in a shape of cross or a star, since applicant has not disclosed that slit indentation in a shape of cross or a star solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with a slit in any shape. Regarding claims 30 and 45, Merry et al discloses the claimed invention except for the surface, extending around the opening in the second wall, lying in a plane substantially perpendicular to a joining direction of the closure element to the connecting tube. It would have been an obvious matter of design choice to modify the surface of Merry et al to lie in a plane substantially perpendicular to a joining direction of the closure element to the connecting tube, since applicant has not disclosed that the surface lie in this specific angle solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the surface lying in any angle.

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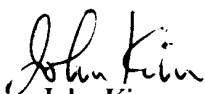
14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. References cited in USPTO-892 form are references considered in the parent application 09/441,182.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (703) 308-2350. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (703) 308-0457. The fax phone number for official response after final action is (703) 305-3599, and the fax phone number for all other official faxes is (703) 305-7718.

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.


John Kim
Primary Examiner
Art Unit 1723

J. Kim
May 29, 2003